

7 Essential Documents in Clinical Trials

Key documents that ensure clinical trials are conducted ethically, safely, and in compliance with regulatory requirements.



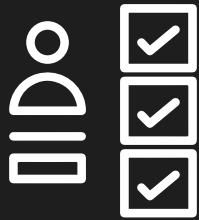
Clinical Trial Protocol

The **Clinical Trial Protocol** is the core document that outlines how the study will be conducted.

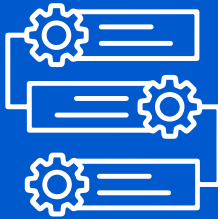
It defines:



Study objectives
and design



Participant
eligibility
criteria



Procedures and
endpoints

Investigator's Brochure (IB)

The **Investigator's Brochure** provides investigators with comprehensive information about the investigational product.

It includes:



Preclinical
data



Clinical data
(if available)



Safety information
and dosing
guidance

Informed Consent Form (ICF)

The **Informed Consent Form** ensures participants understand the study before enrolling.

It explains:



Study purpose
and procedures



Participant
rights and
confidentiality



Potential risks
and benefits

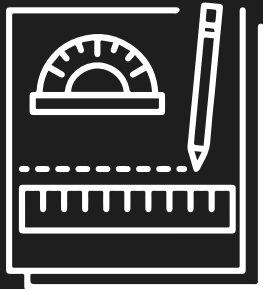
Case Report Forms (CRF)

Case Report Forms are used to collect clinical trial data from each participant.

They capture:



Patient
observations



Study
measurements



Safety and
efficacy data

Ethics Committee Approval

Clinical trials must receive approval from an **Ethics Committee/ Institutional Review Board (IRB)** before starting.

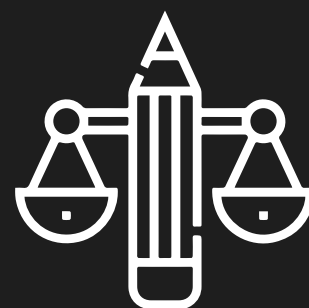
This review ensures:



Protection of
participant
rights



Compliance with
regulatory
standards

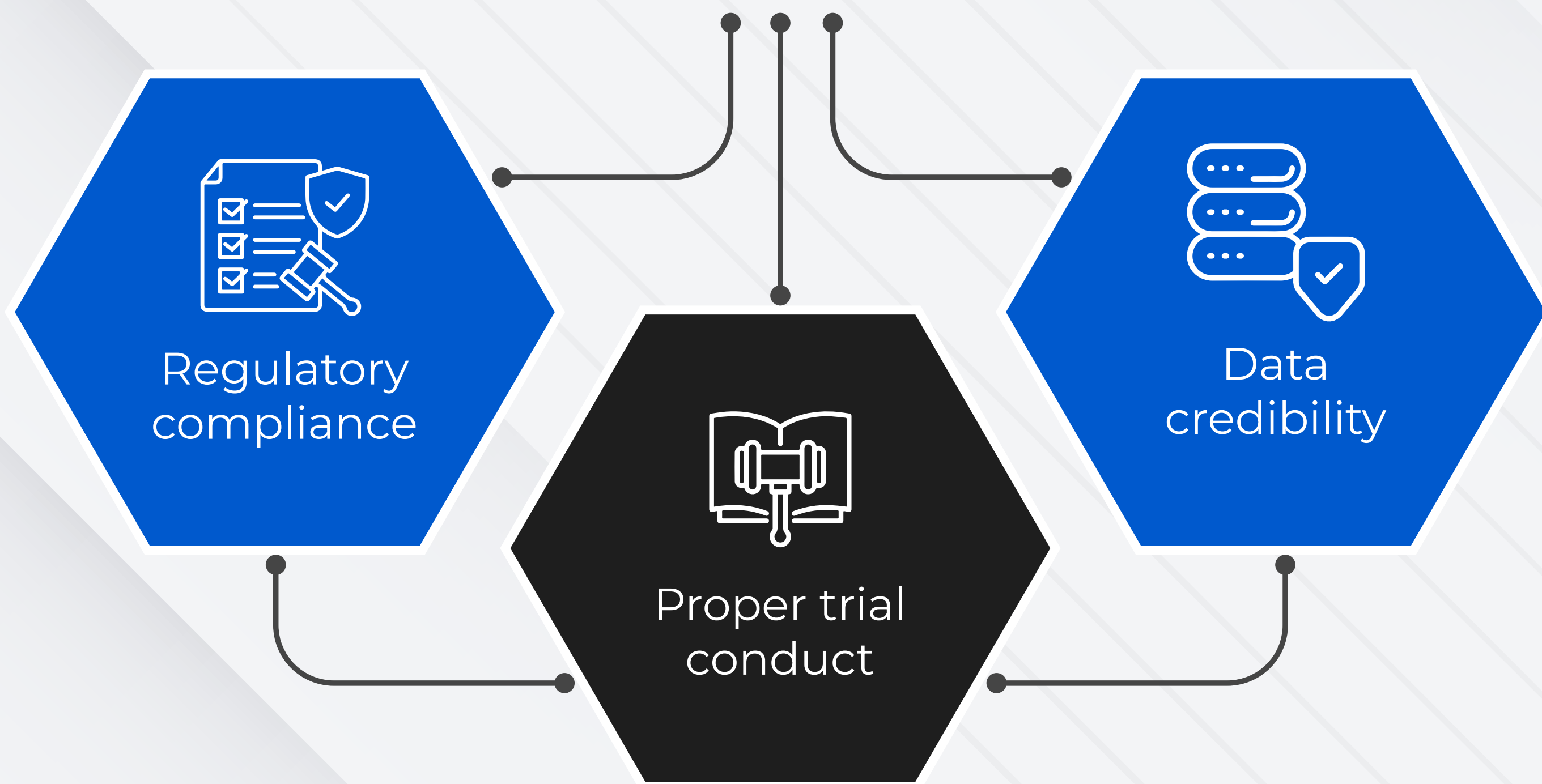


Ethical
study design

Trial Master File (TMF)

The Trial Master File contains all essential documentation that allows regulators to reconstruct the entire clinical trial.

A well-maintained TMF demonstrates:



Clinical Study Report (CSR)

The **Clinical Study Report** is the final comprehensive document that summarizes the trial's conduct and results.

It includes:



Study
methodology



Statistical analysis
and conclusions



Safety and
efficacy
outcomes



**Strong documentation is
the foundation of
successful clinical trials.**

CurexBio supports sponsors with reliable
clinical research solutions.



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